REMARKS

In the Office Action, Claims 1 and 6, 7, and 22-27 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention.

Claims 1, 6, 22, 23, and 25-27 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claims 1 and 22 were rejected under 35 U.S.C. § 102(b) as being anticipated by USP 6,221,622 to Love et al.

Claims 1, 6, 22, 25 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* (BioChem J, 1985, 231:321-328) as evidenced by the teachings of USP 4,339,433 to Kartinos *et al.* and USP 6,235,305 to Mullins *et al.*

Claims 1, 6, and 22-27 are now pending in the application. Claims 1, 6-11 and 22-27 have been rejected. Claims 2-5, 12-21, and 28-33 were previously cancelled. Claim 1 has been amended. Claims 8-11 has been cancelled. Reexamination and reconsideration of the claims are respectfully requested.

Rejection of Claims 1, 6, 7, and 22-27 Under 35 U.S.C. §112, First Paragraph Should be Withdrawn

Claims 1, 6, 7, and 22-27 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention.

Claims 1 and 6-11 and 22-27 were rejected because, as the examiner states, the specification "...does not reasonably provide enablement for the claim-designated method comprising the intraductal administration of any and all amounts of any and all agents recited in the Markush group of Claim1." (Page 3) This rejection is respectfully traversed for the reasons described below.

The Examiner's rejection under 35 U.S.C. §112, first paragraph is based upon the notion that one of ordinary skill in the art would be unable to make and use the entire scope of the claimed invention without undue experimentation. To support such a *prima facie* case, the Examiner states that:

> "[w]hile Applicant has reasonably demonstrated a method for increasing retrievable intraductal fluid, cells and/or other material from a breast duct of a patient comprising the intraductal administration of an effective amount of mannitol that increases the ductal fluid onto a breast duct, Applicant has not demonstrated a method for increasing retrievable intraductal, cells, and/or other material from a breast duct of a patient comprising the intraductal administration of any and all of the agents recited in the Markush group of Claim 1 in any and all amounts to provide the claim designated functional effect to increase secretion of ductal fluid into a breast duct of a patient." (see page 4 second paragraph of Office Action).

To answer the Examiner's rejection, it must be remembered that a claim can encompass "inoperative" embodiments so long as one of ordinary skill can ascertain this without undue experimentation. (Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 2 USPQ2d 1737, 1743 (Fed Cir.). The Examiner has explicitly stated that the specification is enabled for a method of preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to a patient an effective amount of mannitol that increases the ductal fluid collection from a breast duct of a patient (see above). As such, one of

skill in the art could easily conclude that the administration of high molecular weight hygroscopic agents into a breast duct would potentially increase the amount of ductal fluid within the breast duct. Examples of high molecular weight hygroscopic agents can be found in the Markush group of Claim 1 such as sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose, and dextran to name just a few. Since the Applicant has provided the experimental protocol for the administration of agents to a breast duct, one skilled in the art would easily be able to introduce any of the aforementioned high molecular weight hygroscopic agents into the breast duct of a patient (or an animal model) to test for an increase in intraductal fluid. Such an assessment would be routinely performed in the art. Hence, inoperative embodiments encompassed by claim 1 (i.e., agents that are non-hygroscopic) could be easily identified by one of skill in the art without undue experimentation.

Accordingly, Claims 1 and 6-11 and 22-27 are enabled and the rejection should be withdrawn.

Rejection of Claims 1, 6, 22, 23 and 25-27 Under 35 U.S.C. §112, Second Paragraph Should be Withdrawn

Claims 1, 6, 22, 23 and 25-27 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner states that Claim 1 recites the limitation "the secretion of ductal fluid" in lines 3-4 which has insufficient antecedent basis. The Applicant has amended Claim 1 to correct this oversight. The Applicant respectfully requests that the rejection under rejected under 35 U.S.C. §112, second paragraph be withdrawn.

The Rejections Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1 and 22 were rejected under 35 U.S.C. 102(b) as being unpatentable over U.S. Patent No. 6,221,622 to Love. Applicants traverse this rejection.

Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. The Examiner states that "[g]iven the claims the broadest interpretation of the term 'an organic molecule', the Examiner regards the physiological saline washing fluid taught by Love as an 'organic molecule'." The Applicant strongly disagrees.

A saline solution is a sterilized concentration (0.15 molar) of sodium chloride in water. Sodium chloride is an inorganic salt. It is not reasonable for the Examiner to take the position, without providing any evidence to support such an assumption, that a saline solution is an organic molecule. One skilled in the art would clearly recognize that an organic molecule is one that contains carbon as a basic building block. Sodium chloride contains no carbon. Since it is clear that a saline solution is not an organic molecule, the remainder of the Examiner's arguments concerning the Claims 1 and 22 being anticipated by Love cannot stand. There is nothing in Love that either teaches or suggests the use of an organic molecule for increasing the retrievable ductal fluid from a breast duct.

Therefore, because Love does not anticipate neither Claim 1 nor dependent Claim 22, the rejection should be withdrawn.

Claims 1, 6, 22, 25 and 27 were rejected to under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins. Claim 1 was rejected because, as the examiner states "Martyn teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH

and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins)." Applicant respectfully traverses.

Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is selected from the group consisting of a hypotonic solution, a buffered solution, a nonabsorbable biocompatible solution, a protein, a colloid, a sugar, a polymer, mannitol, sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose, polyethyleneglycol (PEG), maltodextrin, dextran, dextran 70, hydroxyethyl starch, fluid gelatin, a synthetic colloid, an antibody, a binding protein, albumin, a hormone, a natural herb, an extract from a natural herb, silymarin, a surfactant, a growth factor, oxytocin, prolactin, an organic molecule, a muscle relaxant, and a ductal orifice dilator. The Examiner has limited Claim 1 to the species nonabsorbable biocompatible solution. Therefore, any reference cited by the Examiner must teach or suggest that a nonabsorbable biocompatible solution must be administered intraductally to a patient and the nonabsorbable biocompatible solution must cause an increase in the retrievable ductal fluid from a breast duct.

Martyn *et al.* describes an *in vivo* experiment in rabbits to measure the effect of prolactin and progesterone on lipogenic-enzyme activity and glycerolipid synthesis. Martyn *et al.* does not teach or suggest a method of using a nonabsorbable biocompatible solution (Blue Dextran 2,000,000) as an agent to increase retrievable ductal fluid from a breast duct. In fact, as evidenced on page 326, Column 1, lines 28-41, as well as Table 4 on page 326, Blue Dextran mixed with Phosphate-buffered saline had no effect on fatty acid synthesis. Therefore, the

method of the present invention cannot be inherent to the method of Martyn *et al.* because there is nothing in Martyn *et al.* that suggests any agent that increases retrievable ductal fluid from a breast duct.

Therefore, because Martyn *et al.* does not anticipate neither Claim 1 nor dependent Claims 6, 22, 25 and 27, the rejection should be withdrawn.

Claims 1, 6, 22, 25 and 27 were rejected to under 35 U.S.C. § 102(b) as being anticipated by Falconer *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins. Claim 1 was rejected because, as the examiner states "...Falconer *et al* teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na+], [K+] and [Cl-] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins)." Applicant respectfully traverses.

Claim 1 recites a method preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is selected from the group consisting of ... a nonabsorbable biocompatible solution. The examiner argues that Falconer *et al* anticipates Claim 1 because it shows that increasing the amounts of prolactin increases the water content of wet tissue in treated mammary gland tissue. Applicant disagrees. Falconer *et al.* describes an in vivo experiment in rabbits to measure the effect of prolactin and ouabain on mammary alveolar tissue. Falconer *et al.* does not teach a method for administering intraductally to a patient an agent that increases retrievable ductal fluid from a breast duct. As evidenced on page 185, Column 1, lines 4-8, Falconer *et al.* explicitly states that "From these

results we conclude that *in vitro* and *in vivo* prolactin has significant influence upon Na+ and K+ content (and therefore Na+/K+ ratio) of mammary alveolar tissue". Alveolar tissue is comprised of glandular tissue and secreting cells that surround the ductal system (emphasis added)(see page 182, Column 2, lines 29-33). Therefore, Falconer *et al.* does not disclose that prolactin and ouabain increases water content in breast ducts, but instead, discloses an increase in water content of the surrounding alveolar tissue. There is no teaching or suggestion in Falconer *et al.* of an agent that increases retrievable ductal fluid from a breast duct.

The Examiner then goes on to state that "...the method taught by Falconer *et al.* is a one step process comprising the intraductal administration of the same ingredient as disclosed by Applicant. Thus, a method for increasing retrieval fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution, is inherent to the method of treatment taught by Falconer." Applicant respectfully traverses.

As mentioned previously, Falconer *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Dextran Blue 2000) as an agent to increase retrievable ductal fluid from a breast duct. There is nothing Falconer *et al.* to suggest that Dextran Blue 2000 can increase the amount of fluid in a breast duct. In fact, as evidenced on page 182, Column 2, lines 13-15, Falconer *et al.* explicitly states that Dextran Blue 2000 is used to "...locate the injected glands at the time of removal". Therefore, the method of the present invention cannot be inherent to the method of Falconer *et al.*, because there is nothing in Falconer *et al.* that suggests any agent that increases retrievable ductal fluid from a breast duct.

Likewise, the Examiner has not provided any reasoning as to why dependent claim 25 is anticipated by Falconer *et al.* There is simply no teaching or suggestion at all in Falconer *et al.* of the use of polyethyleneglycol (PEG), maltodextrin, dextran, or dextran 70 to increase the amount of fluid in a breast duct.

Because Falconer *et al.* does not anticipate neither Claim 1 nor dependent Claims 6, 22, 25 and 27, the rejection should be withdrawn.

CONCLUSION

In light of the amendments and arguments presented above, Applicant respectfully submits that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.023011.

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